CLAIMS

1. A pharmaceutical formulation which comprises a parenterally acceptable carrier or diluent and estramustine phosphate and a basic amino acid.

2. A formulation according to claim 1 wherein the basic amino acid is arginine.

3. A formulation according to claim 1 or 2 wherein estramustine phosphate is in the form of a pharmaceutically acceptable salt for parenteral use.

4. A formulation according to claim 3 wherein the estramustine phosphate is in the form of a salt with arginine, histidine, lysine or N-methyl glucamine.

5. A formulation according to claim 4 wherein the estramustine phosphate is in the form of a salt with arginine or N-methyl glucamine.

6. A formulation according to anyone of the preceding claims comprising estramustine phosphate and arginine in a molar ratio lower than 1:1.

7. A formulation according to claim 6 comprising estramustine phosphate and arginine in a molar ratio of about 1:2.

8. A formulation according to claim 1 which further comprises human albumin, a cyclodextrin or a sulfoalkyl ether cyclodextrin.

9. A formulation according to claim 1 which further comprises human albumin.

10. A formulation according to any one of the preceding claims which is in single infusion dosage form comprising at least 1300 mg of the estramustine phosphate.

11. A formulation according to any one of the preceding claims which is in single infusion dosage form comprising at least 950 mg/m^2 of the estramustine phosphate.

12. A formulation according to claim 10 or 11 wherein the basic amino acid is arginine.

13. A formulation according to any one of the preceding claims for intravenous use.

14. A formulation according to any one of the preceding claims for use in the treatment of cancer.

15. A formulation as claimed in claim 14 wherein the cancer is prostate cancer, breast cancer, melanoma, lung cancer, pancreatic cancer, colorectal cancer, ovarian cancer or cancer of the brain.

16. A formulation according to claim 1 wherein the parenterally acceptable carrier is a physiological solution for parenteral use which contains the basic amino acid, and the estramustine phosphate is in lyophilised form.

17. A product which comprises:

(i) a pharmaceutical formulation which comprises a parenterally acceptable carrier or diluent and estramustine phosphate and a basic amino acid, and

(ii) one or more chemotherapeutic agents,

as a combined preparation for simultaneous, separate or sequential use in anticancer therapy.

18. A product according to claim 17 wherein the basic amino acid is arginine.

19. A product according to claim 17 or 18 wherein the chemotherapeutic agent is selected from the group consisting of taxane derivatives such as paclitaxel and docetaxel; camptothecin and derivatives thereof such as CPT-11 and 9-amino-camptothecin; anthracycline derivatives such as doxorubicin, epirubicin, idarubicin, daunorubicin, alkycycline (4-demethoxy-3'-deamino-3'-aziridinyl-4'-methylsulfonyl-daunorubicin; internal code PNU 159548); etoposide; navelbine; vinblastine; platinum derivatives such as carboplatin and cisplatin; angiogenesis inhibitors such as Sugen SU-5416 and Sugen SU-6668; optionally within liposomal formulations thereof.

20. A product according to claim 17 for intravenous use.

21. A product according to claim 17 for use in the treatment of prostate cancer, breast cancer, melanoma, lung cancer, pancreatic cancer, colorectal cancer, ovarian cancer or cancer of the brain.

22. A formulation as defined in claim 13 for use in suppressing or reducing the side-effects associated with the intravenous administration of estramustine phosphate and pharmaceutically acceptable salts thereof.

23. A formulation according to claim 22 wherein the side effects comprise ulcerative lesions and thrombophlebitis at the site of injection.

24. A product which comprises estramustine phosphate in lyophilised form and a physiological solution for parenteral use containing a basic amino acid.

25. Use, in the manufacture of a medicament for parenteral administration, of estramustine phosphate and a basic amino acid.

26. Use according to claim 25 wherein the medicament is for intravenous administration.

27. A pharmaceutical formulation which comprises a parenterally acceptable carrier or diluent, an antineoplastic agent known to cause ulcerative damages at the site of injection upon intravenous administration, and arginine or a pharmaceutically acceptable salt thereof.

28. A formulation according to claim 27 wherein the antineoplastic agent is selected from the group consisting of anthracycline derivatives such as doxorubicin, epirubicin, idarubicin, daunorubicin and alkycycline (4-demethoxy-3'-deamino-3'-aziridinyl-4'-methylsulfonyl-daunorubicin; internal code PNU 159548); and angiogenesis inhibitors such as Sugen SU-5416 and Sugen SU-6668.

29. Use of arginine, or of pharmaceutically acceptable salts thereof, in the preparation of a medicament for the treatment and prevention of side-effects associated with the intravenous administration of antineoplastic agents.

30. Use according to claim 29 wherein the side-effects comprise ulcerative lesions and thrombophlebitis at the site of injection.

31. Use according to claim 29 wherein the antineoplastic agent is selected from the group consisting of estramustine phosphate; anthracycline derivatives such as doxorubicin, epirubicin, idarubicin, daunorubicin and alkycycline (4-demethoxy-3'-deamino-3'-aziridinyl-4'-methylsulfonyl-daunorubicin; internal code PNU 159548); and angiogenesis inhibitors such as Sugen SU-5416 and Sugen SU-6668.

Add A5